Section II. Revalidation, Termination, and Appeal

2-6. Revalidation.

a. A commercial laboratory whose 18-month validation status has expired will be considered for revalidation upon receipt of a written request from a TM/COR based on the analytical requirements in the upcoming contract(s). The Committee will determine which of the three steps are required for the revalidation process based on the laboratory's previous performance. Normally, Steps 1 (review of qualifications) and 2 (analysis of PE samples) are always required. Step 3 (inspection of laboratory) could be waived if the following criteria are met.

(1) The laboratory's performance on PE samples has been satisfactory,

(2) the laboratory has had no performance problems with previous USACE HTRW projects,

(3) the laboratory has not moved to a new location or had major facility changes at the current location since the last USACE HTRW inspection, and

(4) the laboratory has been inspected by the Committee during a validation/revalidation process within the last three years.

b. During the 18-month validation period, a commercial laboratory shall inform the Coordinator immediately of any major changes in its personnel, equipment, or facilities that could impact the laboratory's performance on any USACE projects. Depending on the scope of changes, a revalidation may be required. The Committee will determine which of the three steps would be needed for the revalidation. The validation status of a commercial laboratory that fails to inform the Coordinator of any major changes may be suspended.

c. A revalidation may also be required when a fully validated laboratory obtains another contract(s) within its 18-month validation period. Based on the contract requirements, the laboratory's validation status, and its previous performance on USACE projects, the Committee will determine which of the three steps are required for a revalidation. Ordinarily, if different analytes or matrices are involved in another contract(s), analysis of additional PE samples is required. If its previous performance has been satisfactory and/or additional PE sample results are acceptable, no further actions are required.

d. A revalidation is also required for laboratories working on ongoing projects that will extend more than six months beyond the validation expiration date of the laboratory. The Coordinator will alert the affected USACE TM/CORs of the pending expiration three months prior to expiration date. A revalidation process should not interfere with the ongoing project unless performance problems are noted during the revalidation process.

2-7. Termination.

a. As a means of measuring a commercial laboratory's performance after validation, the Committee may send additional PE samples on a quarterly or as-needed basis. This depends on the laboratory's past performance on PE sample and/or field sample analyses and on whether the laboratory is currently working on an ongoing USACE HTRW project. The quarterly PE samples could be either single blind or double blind sent by the Committee directly or through a prime contractor. As a minimum, the results are evaluated for compound identification, quantitation, and sample contamination. Results from the analysis of the PE samples will be used by the Committee to verify the laboratory's continuing ability to produce acceptable analytical data. A commercial laboratory's results on these quarterly PE samples will determine its performance as follows:

(1) Acceptable, No Response Required:

Data meets most or all of evaluation criteria as previously described. No response is required.

(2) Acceptable, Response Explaining Deficiencies Required:

Deficiencies exist in the laboratory's performance. Within five working days of receipt of notification from the Coordinator, the laboratory shall send written response to describe the deficiencies and the action(s) taken to correct the deficiencies to the Coordinator.

(3) Unacceptable Performance, Response Explaining Deficiencies Required:

Deficiencies exist in the laboratory's performance to the extent that the Committee has determined that the commercial laboratory has lost its capability to meet the USACE project requirements. Within five days of receipt of notification from the Coordinator, the laboratory shall describe the deficiencies and the

action(s) taken to correct the deficiencies in a letter to the Coordinator.

b. Remedial PE samples may be sent for the failed parameters. It is the sole decision of the Committee to approve or disapprove the quarterly PE sample results and to send remedial PE samples. If a commercial laboratory fails to pass quarterly PE samples, the laboratory may expect, but the Committee is not limited to the following actions: suspension of the laboratory validation status, an additional on-site laboratory inspection, data package audit, a remedial PE sample, and/or contract sanctions.

c. During the 18-month validation period, the performance of the laboratory will be monitored by the USACE TM/CORs, the USACE division laboratories, and the Committee through review of appropriate CQARs prepared by the USACE division laboratories that serve as the project QA laboratories. If a commercial laboratory has performance problems with field sample analysis or data reporting, the USACE TM/CORs and the USACE Division Laboratories should contact the Coordinator immediately to work out necessary corrective and remedial actions. Figure 2-4 can be used to report performance problems with commercial laboratories. Depending on the scope of problems, a commercial laboratory's validation status may be suspended such that the laboratory will not be allowed to analyze any more project samples until the corrective actions are accepted by the Committee and the problems are corrected.

d. While a commercial laboratory is in the process of performing corrective actions, another validated laboratory shall be used until the problems are solved. Should a commercial laboratory fail to solve the problems satisfactorily in a timely manner, the validation status of the laboratory may be revoked for default. The validation status of any laboratory suspended or debarred by other government regulatory agencies may also be terminated by the Committee.

2-8. Appeal. The Coordinator shall advise a commercial laboratory of its right to appeal adverse validation decisions including suspension or termination of validation status. If a commercial laboratory decides to appeal, it should submit a written appeal to the Coordinator within 20 working days from receipt of the laboratory validation report. The Committee will review its decision and send a written response to the laboratory within 20 working days. All review decisions by the Committee are final.

TO: CEMRD-ED-EC FROM :_____ DATE:___/___/____

SUBJECT: PERFORMANCE PROBLEMS WITH COMMERCIAL LABORATORY

Project Name:_____
Location:_____ State:_____
Contract No:_____ TYPE: POL TANK REMOVAL:___HTRW:__

Program: SF:____FUDS:____IRP:____ AF(ACC):____ OTHER:_____
Phase: PA/SI:____ RI/FS:____RD:____ RA:____ RFA:____ RFI:____ CMS:____

USACE Technical Manager:_____
Phone:_____ Address:_____
Government QA Lab:_____ POC:_____
Phone:_____ Address:_____

A-E/Contractor:_____ State:_____
Lab Name:_____
Address:_____
Phone:_____
POC:_____

PROBLEMS ENCOUNTERED:

Figure 2-4 Laboratory Performance Problem Report

PERFORMANCE PROBLEMS WITH COMMERCIAL LABORATORY:

CORRECTIVE ACTIONS TAKEN:

TECHNICAL ASSISTANCE NEEDED FROM THE HTRW MCX:

Figure 2-4 Laboratory Performance Problem Report (continued)